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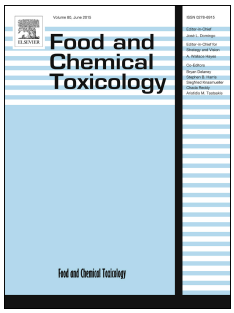

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FDA Regulatory Approach to Steviol Glycosides

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ABSTRACT

Stevia rebaudiana (Bertoni) Bertoni, commonly known as stevia, is a plant native to South America that has been cultivated for hundreds of years. In 1995, FDA revised its import alert on stevia leaves and extracts to allow for their use as dietary ingredients in dietary supplements. In 2007, the Joint FAO/WHO Expert Committee on Food Additives established a safe level of intake and specifications for steviol glycosides that included a minimum purity of 95% of seven named steviol glycosides. In 2008, FDA responded without questions to a Generally Recognized as Safe (GRAS) notice for the use of highly purified steviol glycosides obtained from stevia leaves as a general purpose sweetener in food. Due to the existing import alert, FDA filed, evaluated, and has not objected to more than 50 GRAS notices for the use of various high-purity steviol glycosides as sweeteners in food. In this paper, we highlight FDA's practices for filing and evaluating GRAS notices for steviol glycosides. We also provide a summary of the data and information presented in GRAS notices for steviol glycosides in the GRAS Notification program. FDA has received a new wave of GRAS notices that include alternative biotechnological methods for production of steviol glycosides.

Keywords: FDA, Generally Recognized as Safe, GRAS, stevia, sweetener, steviol glycosides